DETECTION OF DIASTOLIC HEART FAILURE

Technical Field

The present invention relates to an implantable medical apparatus for

5   detecting diastolic heart failure, DHF, comprising a DHF determining device for

determining at least one blood pressure parameter for detecting a DHF state of the

heart of a patient. The invention also relates to a pacemaker provided with such an

apparatus, and a method of detecting DHF, comprising the step of determining at

least one blood pressure parameter for detecting a DHF state of the heart of a

10   patient.

Background

There is a growing recognition that congestive heart failure caused by a

predominant abnormality in the diastolic function, i.e. diastolic heart failure, DHF,

15   is both common and causes significant morbidity and mortality. Therefore early

detection of DHF is important. Patients do not, however, seem to have symptoms

at an early stage. In addition it has been hard to separate diastolic and systolic

heart failure and they may also exist simultaneously.

It has been discovered that among the few parameters, separating

20   diastolic heart failure from systolic heart failure, are certain blood pressure

parameters obtained during work of the patient. Thus US 6 438 408 describes an

implantable medical device for monitoring congestive heart failure, CHF. A plurality

of heart failure parameters indicative of the state of the heart failure are measured

employing EGMs, blood pressures including absolute pressures, developed

25   pressures (= systolic pressures − diastolic pressures) and the time derivative

dP/dt, as well as heart chamber volumes. One of these parameters is the

relaxation or contraction time constant τ of the heart chamber. τ is calculated from

a continuous pressure signal and is the drop in ventricular pressure at the end of

systole and in the first part of diastole. The τ parameter is thus a general

30   parameter reflecting the relaxation process.

According to an article by Dalane W. Kitzman et al., Pathophysiological

Characterization of Isolated Diastolic Heart Failure in Comparison to Systolic Heart

Failure, JAMA vol. 288, No. 17, 2144, November 6, 2002 the exercise pulse

pressure is one parameter separating systolic heart failure from diastolic heart failure.

The purpose of the present invention is to utilize this knowledge to propose a technique for detecting DHF, preferably at an early stage when the patient still does not seem to have any symptoms, based on measurement of pulse pressure under work.

Disclosure of the Invention

This purpose is obtained by an apparatus, a pacemaker and a method of the kind mentioned in the introductory portion of the description and having the characterizing features of claims 1, 10 and 13 respectively.

Thus with the present invention the reduced peak and submaximal exercise performance of DHF patients is utilized for detecting DHF. With the technique according to the invention it is possible to detect DHF at an early stage, often before the patient seem to have any symptoms.

In the present invention the workload situation of the patient must be identified, and therefore, according to an advantageous embodiment of the apparatus according to the invention, an activity sensor is provided for determining the workload of the patient.

According to another advantageous embodiment of the apparatus according to the invention an averaging means is provided to form an average value of pulse pressures during a plurality of cardiac cycles with said workload situation and an average value of pulse pressures measured during a plurality of cardiac cycles with the patient in rest. In this way the quality of the pulse pressure measurements is improved.

According to other advantageous embodiments of the apparatus according to the invention a wireless communication means is connected to said comparison means for automatically sending the results of the comparison of measured pulse pressures with said reference values to external receiver means, or a storing means is provided for storing the results of the comparison of measured pulse pressures with said reference values. Thus if the pulse pressure has risen above the reference value in a predetermined way this condition is automatically transmitted to a physician or stored for transmission in connection with a follow-up.

According to still other advantageous embodiments of the apparatus according to the invention said pressure measuring means comprise a pressure sensor adapted for placement in right ventricle or coronary veins of the patient's heart, and said pressure measuring means are adapted to determine maximum and minimum pressures in a cardiac cycle. It is preferred to place the pressure sensor in the right ventricle or the coronary veins, since the pressures in these places reflect the morphology of the left ventricular or aortic pulse pressure, especially with regard to maximum and minimum pressures.

The invention also relates to a pacemaker provided with the apparatus for detecting DHF and control means for optimising pacing therapy depending on the result of the comparison of said measured pulse pressures with said predetermined reference values. The pressure measuring means of the apparatus according to the invention then preferably comprises a pressure sensor connected to the pacemaker, since it can monitor the pulse pressure of its carrier for long periods. This is an advantage since evolvement of DHF is a slow process.

An advantageous embodiment of the pacemaker according to the invention comprises a rate responsive sensor for use as activity sensor for determining the workload situation of the patient. Even the pressure sensor of the pacemaker can be used as activity sensor.

According to an advantageous embodiment of the method according to the invention photo-plethysmographic signals are sensed for determining the pulse pressure, since it has been discovered that photo-plethysmographic signals obtained by a sensor placed close to the tissue where a pacemaker or ICD is implanted contain information about pulse pressure.

As mentioned above the measured pulse pressure is compared with a predetermined reference value, and according to an advantageous embodiment of the apparatus and the method according to the invention said pulse pressure in a cardiac cycle is measured for a predetermined workload situation and a rest situation of the patient, and the difference between said pulse pressures measured in said workload and rest situations is compared with a predetermined reference value for said difference for DHF detection. A condition of DHF is identified by a higher pulse pressure during workload than a patient with a systolic heart failure would have. The reference value for detection of DHF is preferably obtained from measurements on the patient at an early stage of the implantation period of the

apparatus or pacemaker. The patient is supposed not to suffer from DHF at the time of implantation. Therefore, according to an advantageous embodiment of the method according to the invention, pulse pressures are measured for different workloads of the patient and for the patient in rest at an early time, when the

5   patient is not suffering from DHF, for determining said reference values. These pulse pressures from an early stage can also be measured for a certain period of time and typical pulse pressures during an identified workload and during rest are gathered and averaged and then stored for later use as reference values for comparison purposes. If later the measured pulse pressure, or average pulse

10   pressure measured during several cardiac cycles, exceeds the reference value determined in this way by a prescribed amount x%, this is used as an indication of DHF.

Brief Description of the Drawings

15   To explain the invention in greater detail an embodiment of the invention will now be described with reference to the drawings on which figure1 is a diagram showing the left ventricular and aortic pressures as a function of time, figure 2 shows a block diagram of an embodiment of a pacemaker according to the invention, figure 3 is a flow chart illustrating the overall collection of pulse pressure

20   data in an embodiment of the apparatus according to the invention, and figure 4 is a flow chart explaining in greater detail an example of the procedure for obtaining pulse pressure data according to the present invention.

Description of a Preferred Embodiment

25   In the following an embodiment of the invention using a pressure sensor will be described, and by the expression pulse pressure is meant the varying pressure in aorta during a cardiac cycle.

        The above-mentioned pulse pressure can be obtained from the pressure measured in the left ventricle. In figure 1 the top curve shows the left ventricular

30   pressure and the curve below the aortic pressure as a function of time. The magnitude of the pressures are indicated in arbitrary units in the figure.

        The asterisks in the curves of figure 1 denote time points for the maxima and minima of the time derivative of the left ventricular pressure, $dLVP/dt_{max}$ and

$dLVP/dt_{min}$ respectively. As the aortic valves open close to the point $dLVP/dt_{max}$, the aortic pressure is close to the left ventricular pressure at this point of time.

During the period from $dLVP/dt_{max}$ to $dLVP/dt_{min}$ blood flows into aorta. The maximum of aortic pressure is situated in this period. The pulse pressure can

5   consequently be obtained from left ventricular pressure by subtracting the pressure at the point of $dLVP/dt_{max}$ from the maximum of the left ventricular pressure obtained during the mentioned period.

If the conditions are such that pressure signals from other parts of the hemodynamic system are morphologically similar to the left ventricular pressure,

10   these signals can also be used for determining the pulse pressure in the present invention, since only relative changes have to be determined for detecting DHF.

Figure 2 shows an embodiment of a pacemaker according to the invention comprising basic pacemaker circuits 20. A pressure sensor 2 is located in the right ventricle 18 of a patient's heart and connected to the pacemaker 4. The signals

15   from the pressure sensor 2 are supplied to an A/D-converter 10. After A/D-conversion the time derivative of the signal is formed in a derivation unit 16. The time derivative of the pressure signals are filtered in the low pass filter 12 before supply to the microprocessor and supporting circuits 14. Since time derivation promotes high frequency noise, it is advisable to eliminate in this way possible

20   false peaks and valleys, which could be interpreted as $dLVP/dt_{max}$ and $dLVP/dt_{min}$. The filtered signals are supplied regularly into microprocessor and supporting circuits 14.

Located in the pacemaker 4 is an activity sensor 6 which is connected to an activity measuring unit 8 for determining the workload of the patient. A

25   corresponding activity or workload signal is fed to the microprocessor and supporting circuits 14.

Figure 3 is a flow chart illustrating an example of the overall process for collecting pulse pressure data. The development of DHF is a slow process as mentioned. A timer, at 26 in figure 3, is therefore provided for activating pulse

30   pressure measurements on a regular basis for reducing the current drain and releasing microprocessor power.

Collection of pulse pressure data is performed for different workloads of the patient, at 22 in figure 3. As mentioned above the collection process is activated by a timer, at 26, and therefore the process has to wait for activation by

the timer before starting, at 24. As the process is started, at 28, pulse pressure data are stored in different intermediate memory locations depending on the workload of the patient, at 30. Addresses to this memory locations are obtained from a table pointed to by the workload or activity measuring unit depending on the

5   workload or activity,. at 32. Pulse pressure data from the intermediate memory is then stored in another memory according to the address obtained in the preceding step for later analysis, at 34 .

To improve the accuracy of the data stored the procedure of storing pulse pressure data can be performed by forming a floating mean value. One way to do

10   this is to add a fraction 1/k of a new pulse pressure value $P(i)$ to the pulse pressure value stored P_{stored} at the memory location pointed to by the activity measuring unit and form a mean value P_{store} according to the following equation

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$$P_{store} = \frac{P(i) + P_{stored} \times (k - 1)}{k}$$

Figure 4 is a flow chart illustrating in greater detail the procedure for

20   obtaining the pulse pressure. P_{max} and P_{min} denote temporary storages of maximum and minimum aortic pressures.

In order to start the pulse pressure measurements a QRS has to be detected , at 38 in figure 4, after reset of P_{max} and P_{min} , at 36. Pressure samples P(i) are then stored continuously together with the time derivative $dP(i)/dt$ for

25   comparison, at 40. A certain number of contiguous samples have to exist simultaneously, so that the above-mentioned filtering of the time derivative of the pressure is in accordance with the length of the filter coefficients. Care must be taken so that the delay in the filter influences the selection of corresponding pressure samples in a timely fashion, i.e. the pressure samples are picked with the

30   same delay.

When dP/dt_{max} has been found, at 42 and 44, the pressure at that point in time is selected as the minimum pressure P_{min}. The pressure then rises in the aorta and the maximum pressure during systole occurs in the period between dP/dt_{max} and $dP/dtmin$, cf. the description of figure 1. In the process illustrated in

35   figure 4 a simplified approach is used for determining maximum pressure P_{max}. Instead of determing the point of time for dP/dt_{min} a timer is started at the point of

dP/dt_{max}, at 46 in figure 4 and P_{max} is determined according to steps 48, 50, 52, 54 till timer overflow, at 56. Such a timer procedure is justified since the systolic time period in practice varies little. The pulse pressure is then obtained by subtracting P_{min} from P_{max}, at 58, which is the output of the process.

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Instead of determining the pulse pressure with the aid of pressure sensors it can be determined by photo-plethysmography. Photo-plethysmographic signals from a sensor placed close to the tissue at the location of the implanted pacemaker or ICD contains information on pulse pressure. Thus such photo-pletysmographic

10   signals can be used as an alternative for determining the pulse pressure.